



## Risk Assessment, the Environment, and Public Health

**Joseph V. Rodricks**

ENVIRON International Corporation, Arlington, VA 22203 USA

In the minds of many observers, the phrase "risk assessment" conjures up a specific and scientifically suspect methodology that is applied by the U.S. Environmental Protection Agency and other regulatory bodies to examine questions about risks to human health that can not be fully answered using traditional scientific methods. More specifically, the phrase is often thought to refer to the particular methods and assumptions EPA applies to extrapolate from sets of human or (more commonly) animal carcinogenicity data, obtained under conditions of relatively intense exposures to the carcinogen, to develop quantitative estimates of health risks that are said to be caused by the carcinogen at the much less intense exposures experienced by most human populations. If they think the risks projected using these methods are excessive (according to criteria set forth in the law under which the carcinogen is regulated), the EPA and its sister regulatory agencies (FDA, OSHA, CPSC) will make what is called a risk management decision to bring about reductions in the projected risks (1).

Although this view of risk assessment captures much of its present practice and application, it is deficient in two important respects. First, it incorrectly assumes that the specific risk assessment methodology used by the regulatory agencies fully defines its practice, and second, it fails to consider the possibility that risk assessment can serve much broader and socially useful purposes than regulation of carcinogens and other toxic substances of industrial origin. I attempt here to stimulate thinking about possible broader uses of risk assessment in identifying and solving public health problems of many types and also suggest how its practice can serve as a highly systematic guide to public health research. I also attempt to make the case that a less restrictive view of how risk assessment should be practiced needs to be encouraged; indeed, it is necessary that we change our thinking about the content and practice of risk assessment if it is to serve broader purposes.

I begin with a brief review of how and why risk assessment entered the lives of regulatory agencies and of the reasons that drove the regulators to adopt specific methods and assumptions. I go on to dis-

cuss current practices and the scientific limitations that attend them. This discussion sets the stage for an elaboration of my views regarding possible broader applications of risk assessment and of the methodological issues that need to be explored to realize its full public health potential. My purpose here is only to provoke such exploration, and so I do not deal with detailed methodological questions.

These proposals to enlarge the practice and scope of risk assessment are based on the premise that public health resources should be devoted to reducing risks in at least rough proportion to the toll they take on human health and that risk assessment, properly conceived and practiced, is the appropriate tool for assigning risks their rightful order. Seen from this perspective risk assessment should be a principal component of public health programs everywhere, both to guide research and the allocation of research funds and to inform decisions about improving public health. I return to these ultimate issues in the closing sections of the paper.

### Origins and Evolution of the Practice of Chemical Risk Assessment

Although safety engineers and radiation biologists had been practicing risk assessment, or something akin to it, for several decades before the 1970s, it was later that federal regulatory agencies began to officially incorporate procedures they referred to as risk assessment (2). They did so not because of a scientifically driven imperative, but because many of the laws they were charged with enforcing required the agencies to answer questions for which directly relevant empirical evidence could not be developed. The typical problem faced by regulators involved situations in which large numbers of people, sometimes nearly the entire population, were or could be exposed to relatively low levels of chemical substances (in consumer products and medicines, the workplace, and in air, water, foods, and soils) that had been identified as hazardous to health (toxic), but only under conditions of relatively intense exposures. The regulators' problems were worsened by the fact that most of the scientific data used to identify the toxic properties of chemicals, especially those of a

Risks to human health arise from the environment in diverse ways and from many sources. Although there are many social forces to be considered when efforts are made to protect human health, it would seem that public health resources should be devoted to reducing risks arising from the environment in at least rough proportion to the toll they take on human health. Risk assessment, properly conceived and practiced, is the appropriate tool for assigning risks their rightful order and should be a principal component of public health programs everywhere. The successful application of risk assessments to such goals depends on the development of a broader view of its nature and content than has been customarily adopted. *Key words:* carcinogens, chemical toxicity, default assumptions, nutrients, pathogens, radiation, regulation, risk assessment, risk management, risk policy. *Environ Health Perspect* 102:258-264 (1994)

chronic nature, involved studies in experimental animals, typically rodents. Thus, regulatory officials were faced with two fundamental questions which, in most cases, could not be fully answered using available scientific methods: 1) what risks to human health exist in the range of chemical exposures below the relatively intense and narrow range under which risks could be directly measured? and 2) what could be said about risks to human health when experimental animals were the only subjects in which risks to health had been measured?

These questions were not new in the 1970s; indeed, regulators and others involved in setting or recommending limits on human exposures to chemical substances had developed practical methods for dealing with them nearly three decades earlier. These individuals did not refer to their practices as risk assessment, and, in fact, they did not seem to recognize the risk assessment-risk management distinction that is now seen as important in the standard-setting process. These early practitioners assumed that all chemical substances, natural and synthetic, would pose some type of health hazard if exposures exceeded a so-called threshold level and that, with some important qualifications, experimental animals could be used to identify the types of hazards a substance

Address correspondence to J.V. Rodricks, ENVIRON International Corporation, 4350 North Fairfax Drive, Suite 300, Arlington, VA 22203 USA.

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might pose to people and the conditions under which these toxic hazards might exist (3). So-called safety factors were introduced to compensate for uncertainties in the toxicology data and in their applicability to large human populations, and recommended or required limits on human exposures were usually set at some small fraction of the exposure levels that could be clearly documented as hazardous. It was then assumed that as long as human exposures did not exceed the "safe" levels, the hazardous properties of chemical substances would not be expressed. For many types of chemical toxicity, this practice, in somewhat refined form, continues to this day (3-5).

Although there are technical difficulties with this approach to dealing with low exposure risks of toxicity, they are not relevant to the present discussion. What is relevant is the fact that, during the late 1960s and early 1970s, federal regulatory agencies had to come to grips with an increasingly important problem for which many scientists considered the safety factor approach to be inappropriate, even dangerous. This was the problem of chemicals that had been shown under certain conditions to increase the risk of cancers in humans or experimental animals—substances operationally referred to as carcinogens. As with other forms of toxicity, cancer risks could normally be directly measured only under highly restricted conditions, typically in groups of intensely exposed individuals (those who worked directly with the chemical or those receiving high doses of certain drugs) or in similarly exposed laboratory animals.

As early as the 1940s, some scientists had come to the view that chemical carcinogens caused damage by biological mechanisms that were of a radically different kind from those that produced other forms of toxicity (6,7). In part borrowing their ideas from recent developments in the biology of radiation-induced cancers, these scientists put forth what is referred to as the "no-threshold" hypothesis. This hypothesis holds that any exposure to a carcinogen that reaches and interacts with a critical biological target can increase the probability (the risk) of cancer development. If the no-threshold hypothesis were true, then it would be inappropriate to use a scheme for establishing safe limits that assumes the existence of a threshold dose. The no-threshold hypothesis had its earliest and most extreme influence on public policy in the development of the 1958 Food and Color Additive Amendments to the Federal Food, Drug and Cosmetic Act, which include the Delaney Clause. The Delaney Clause forbids the intentional and direct addition of any human or animal

carcinogen to food on the ground that no safe level of human exposure can be identified for such an agent (8). (These same amendments allow the addition of substances causing any other type of toxicity to food, as long as the expected human intake is below the toxicity level by a sufficiently wide margin; i.e., they implicitly adopt the threshold hypothesis.) Although no other laws dealing with environmental chemicals, with the possible exception of the Safe Drinking Water Act, take such an extreme position on carcinogens, many single them out for special treatment (5,9).

The cumulative effects of several inter-related activities began to be felt in the 1970s and forced regulatory agencies to deal with carcinogens more directly and aggressively than they had up until that time (2,5). In the years before the 1970s, public health and regulatory officials had banned the commercial uses of a few chemical carcinogens and had called for exposure reductions for a few others, usually to concentrations that were just below the detection limits of available methods of chemical analysis (the "out-of-sight, out-of-mind" approach). Many carcinogens found in the environment were simply ignored because there was no obvious means to cope with them.

By the early 1970s this state of affairs came to be seen as unacceptable. The rate at which commercially important chemicals were identified as carcinogens, mostly through animal tests, had increased rapidly during the 1960s and increased even more rapidly into the 1970s. Moreover, analytical chemists had been improving their detection capabilities with even greater speed and had discovered more chemicals in more environmental media at lower and lower levels. And, as mentioned earlier, a spate of new laws enacted in the same time period calling for strict controls on human exposures to potentially dangerous chemicals forced regulators to confront these emerging facts (1).

It was generally assumed that with few exceptions, such as intentionally introduced food additives, the imposition of outright bans on the production and use of many commercially important products because of their carcinogenic properties was not a viable approach, and it was certainly not feasible for many industrial by-products and wastes. Turning to the analytical chemist for decision-making was not useful if the "below detection limit" approach to standard setting was to be used because detection limits could continually be reduced. Such an unstable approach to setting limits on exposures was additionally burdened with the awkward fact that the magnitudes of the health risks associated with carcinogens are surely

unrelated to the abilities of analytical chemists to detect them (10). For these and other reasons, regulatory agencies such as EPA and FDA began in the mid-1970s to adopt methods that had been discussed in the scientific literature for assessing low-dose risks from chemical carcinogens (7,11,12).

The regulators recognized that several assumptions, some unsupported by any direct empirical evidence, had to be employed to assess carcinogenic risks. The nature of the dose-risk relation at low doses had to be assumed because it could not be uncovered empirically. In many cases several different sets of animal data had to be evaluated and decisions made about which set, if any, applied to human beings. The particular measure of dose at which humans and rodents could be said to be at equal risk also had to be assumed. The list of assumptions needed to complete a risk assessment could be quite long (1).

Regulators recognized the need for assumptions and noted that to achieve consistency, they would adopt specific sets of assumptions that would be generically applied to all carcinogens. The agencies specified, for example, that animal evidence of carcinogenicity would be recognized as useful for assessing human risk. They specified that carcinogenic risks would be estimated using the most sensitive animal model and linear, no-threshold, dose-risk models, and that statistical upper confidence limits would be used rather than best estimates. These and several other assumptions (regarding, for example, the methods used to estimate the magnitude of possible human exposures to carcinogens) were adopted as what the National Academy of Sciences, in an influential 1983 report, termed "science policy" choices in risk assessment (1,2,12). When science cannot provide definitive answers, policies would be imposed because not doing so would result in socially unacceptable conclusions—that nothing at all could be said about the risks to human health that might obtain at low doses (10). Better to use such default assumptions, as long as they were not clearly inconsistent with current scientific knowledge, than to adopt approaches to regulation that took no account of the possible magnitude of the health problem or to admit such ignorance of health consequences that no regulation could be justified (1).

Once defaults were adopted and low-dose risks from carcinogens were estimated, risk managers stepped in to define the ranges of risk that could be considered sufficiently low to protect public health. Decisions about "acceptable," "tolerable," or "insignificant" levels of risk became common and brought new controversies (11).

## Regulatory Practices and Their Limitations

The regulatory practice of risk assessment is characterized by the use of specific default assumptions that are designed to allow the completion of risk assessments when data and knowledge are incomplete, as of course they always are. Although the agencies have acknowledged that, in certain cases, data may become available to show that one or more of the default assumptions is not supportable, and that alternative assumptions have greater scientific merit, there are very few cases (and none of major significance) in which regulators have found the data supporting an alternative assumption sufficiently certain to warrant a departure from the default. Perhaps the reluctance of regulators to abandon standard default assumptions is explained by the fact that most of the alternative assumptions that have so far been suggested result in a conclusion that the chemical under evaluation carries less risk than is suggested when the regulatory defaults are employed. This observation is explained by the fact that the standard sets of default assumptions were selected by regulators to ensure (to the extent this could be plausibly guessed at) that risks would not be underestimated—in unfortunate but widely used parlance, the default assumptions are said to be conservative. Moving away from the standard default assumptions could thus lead to a potentially dangerous underestimation of human risk if the basis for doing so were incorrect, so regulators have sought a high degree of scientific certainty in the data brought forward to support alternative assumptions in risk assessment (13,14).

Because achieving a high degree of scientific certainty in matters of this type is rare (and regulators have not specified the degree of certainty that they would like to see achieved), the regulatory default assumptions, most of which were adopted in the 1970s and which have undergone little change since, have effectively become standardized.

Criticisms of regulatory risk assessment practice, which range from the uninformed to the highly thoughtful, arose on almost the first day regulators engaged in it. Many of these, especially in the early days, challenged the very idea that decisions should be based on the notion that there was some level of acceptable risk, and argued that the only appropriate goal was no risk. These types of challenges reflect fundamental philosophical differences regarding how risk-free we should or can seek to make our environment and are not of interest here. What is of interest are those criticisms that have been directed at the practice of risk assessment.

Most of this criticism falls into two broad categories. One pertains to what many perceive as the excessive conservatism of the standard default assumptions. It is argued, most often and for obvious reasons by those whose products, emissions, and wastes are under regulatory challenge, that the cumulative effect of adopting many such assumptions results not only in assurance that risk is not underestimated, but guarantees that risks are greatly overestimated. These critics ask regulators to adopt default assumptions of less extreme nature to avoid such undesirable outcomes (15,16). Some criticisms have entered from the opposite direction; the prominent one is that regulatory risk assessments of carcinogens take no account of the possibility of sensitive subpopulations, but such criticisms have been less common (17).

The second group of critics argues that regulators are too reluctant to abandon default assumptions when data are available to show that alternatives have greater scientific merit. Instead of seeking the phantom goal of scientific certainty before opting to depart from standard assumptions, regulators should, these critics argue, choose on a chemical-specific basis to consider all those assumptions that have some degree of scientific support. These critics do not ask the regulators to ignore uncertainties, but rather urge that all available scientific data be used, that the full range of risks that can be inferred from these data be presented and, if possible, that those risks having the greatest scientific support be highlighted. When presented with the results of such a risk assessment, risk managers—those who need to decide whether and to what degree risks need to be reduced—are free to adopt more or less conservative approaches depending on the context of their decision-making and the requirements of applicable laws (18). If the context requires a high degree of risk aversion, policy makers can base their decisions on the high end of the risk range, while acknowledging that other (lower) estimates may be equally well or even better supported. Other contexts for decision-making may result in the use of other sets of assumptions and the risks derived from them.

Critics of regulatory practices who promote this approach also argue that it minimizes the role of the risk assessor in ultimate questions of policy. Under this approach, risk assessors are not asked to discard data because they have judged them to be “too uncertain” to use in decision-making, nor have they been forced to constrain their choices of assumptions so that risk managers are presented with only a limited portion of the range of risks that

might plausibly be inferred from available data and basic scientific understanding. Decisions regarding the degree of conservatism ultimately to be adopted are placed where they should be—squarely in the hands of policy makers (14,16). The approach to risk assessment favored by this second group of critics is the one I advocate below, as I turn to a discussion of broader uses of this tool in the formulation of public health policies.

Although, as I have said, the critics of regulatory practice have so far had little practical effect, there are signs that EPA and other regulatory agencies are seeking ways to make fuller use of scientific information in risk assessment and to incorporate uncertainty into decision-making. If this trend continues and is held to scientifically rigorous standards, it should lead not only to better regulatory decisions, but should also encourage research that will yield better understanding of health risks from low-level exposures to chemicals in the environment. Exploration of this last issue will lead us to a discussion of how risk assessment, properly conceived, can be applied to a greater array of public health problems than those associated with industrial products and by-products.

## Risk Assessment and Research

The typical question regulatory risk assessors attempt to answer, the size of the public health problem associated with exposures to carcinogens and other toxic substances, is in theory subject to empirical investigation. There are, however, serious deficiencies in our available research tools, so we are at present prevented from gathering directly relevant scientific data (11). It is nevertheless the case that substantial progress is being made in both the experimental and epidemiological sciences, and several novel and potentially highly telling methodologies are being applied to selected problems. These efforts need both to be encouraged and directed toward specific public health objectives. The practice of risk assessment, if it is not constrained by unyielding adherence to standard regulatory assumptions, can greatly assist the achievement of these ends.

If risk assessors are free to explore the full spectrum of inferences regarding health risks that can be drawn from all available data on specific chemicals, particularly those pertaining to their underlying mechanisms of biological action, two useful outcomes can be achieved. First, as mentioned previously, the complete state of present knowledge and its associated uncertainties can be presented to risk managers, and better informed regulations should follow. But a possibly more important goal might also be realized. I suggest

that there is no better guide to public health research than a thoroughly elaborated risk assessment.

Risk assessment, as I suggest it should be conceived, is a highly systematic means for organizing available information and knowledge and for specifying the degree of scientific certainty associated with each of the sets of data, models, and assumptions that are needed to reach conclusions regarding health risks of any type. In a thoroughly realized risk assessment, the significant gaps in information and knowledge that limit understanding of the nature and size of the public health problem being explored are laid bare, and highly specific lines of investigation that can advance understanding are thereby suggested. Close collaboration between risk assessors and research scientists can immensely profit the professional lives of both. To the extent regulatory agencies encourage risk assessors to explore the ramifications of all available data, no matter how incomplete (in the manner suggested by the second group of critics mentioned above), they will contribute to the efforts of the research community to develop and apply methods that will have a significant impact on our understanding of the threats to public health posed by chemical exposures and by other environmental hazards as well.

Risk assessment is the means by which currently available information about public health problems arising in the environment is organized and understood. The results of a risk assessment, most specifically the analysis of uncertainties contained in any thorough assessment, point the way to new research efforts. The results of these new research efforts are used to increase the accuracy of the risk assessment. The cycle continues until we are satisfied that our understanding of the nature and size of the public health problem is sufficiently complete.

Institutional mechanisms to ensure this type of close collaboration between the research and risk assessment communities are not well established, although elements of it are in evidence. Perhaps it is time to consider more carefully how to create such arrangements.

### **Toward a Broader View of Risk Assessment**

Risk assessment should primarily be seen as a framework within which all available information and knowledge pertaining to the risk at hand can be organized in a highly systematic way, with the objectives of characterizing the nature and size of the risk and of specifying the degree of scientific certainty that can be attached to the various sets of data, models, and assumptions used to produce the risk estimates. This

broad view of risk assessment, as against the view that it involves only the application of the specific sets of default options adopted by regulatory agencies, is, in fact, close to that put forth by the 1983 National Academy of Sciences report (1), mentioned earlier. The members of the NAS Committee that produced the report recognized the need for standardized default options (without these regulators could reach no conclusions about risk or would be tempted to adopt on a case-by-case basis those assumptions that might lead to the most convenient outcome) but recommended that efforts be made to explore all available data and alternative assumptions. The committee's recommendations did not go as far as those suggested here, but certainly pointed in the same direction (1).

### **Content of Risk Assessment**

Besides those advantages already mentioned, this broader conception of risk assessment would seem to offer the advantage that one can envision its application to a broad array of public health problems of environmental origin. Before exploring this possibility, it is useful to outline the general framework for risk assessment proposed by the NAS committee in 1983 and widely adhered to since. Risk assessment was seen as a four-step process. Although some of the terms used to describe the steps and their context came from the language of chemical toxicology (because the committee was primarily concerned with such hazards), the analytic content of each step, and the way in which the steps are integrated, would seem to be applicable to other types of environmental threats.

*Hazard identification* is the name given to step one. In the context of chemical toxicity, this step involves identifying from the available scientific literature the types of toxic effects (nervous system damage, birth defects, skin irritation, cancer, etc.) that the chemical can cause or contribute to. It also involves, as every step does, a full characterization of the degree of scientific certainty with which toxic effects observed under certain conditions (e.g., in populations of exposed workers or in certain species of laboratory animals) can be said to hold for the population whose risks are being assessed.

The second step of risk assessment involves what the committee called *dose-response assessment*. This term was borrowed directly from the domain of chemical toxicity, although it is also used in the area of radiation-induced risks. In this step the risk assessor attempts to provide a quantitative description, again with its associated uncertainties, of the relationship between the magnitude, duration, frequen-

cy, or even timing of the chemical exposure and the severity or frequency of occurrence, or both, of the chemical's hazards that is likely to hold in the range of doses experienced by the population whose risk is under assessment.

Now the risk assessor moves to step three, the *human exposure assessment*: what range of exposures is experienced by the human population whose risk is being assessed? Indeed, just what populations are being evaluated, and how are exposures to the chemical agent distributed within them?

Having identified the types of hazards associated with a chemical and how the risks of those hazards occurring relate to exposure, and having identified the exposures actually experienced by the populations of interest, the risk assessor is ready for step four, the *risk characterization*, wherein the assessor describes the particular risks likely to be experienced by the population of interest under its actual or expected exposure conditions, based on the information and analysis assembled in the first three steps. Risk characterization involves not only integration of knowledge, but also a full exposition of the degree of scientific certainty that can be attached to that knowledge (1).

This broad four-step framework can in theory be applied to all types of health threats that arise in the environment. The specific methodologies and assumptions to be applied in each of the four steps will vary according to the specific environmental agent(s) (see next section for a definition of this term) and the strength and nature of available scientific data and our general understanding of its effects on human health. The general framework for risk assessment outlined above is the central organizing device under which the available knowledge relevant to the particular environmental source of risk is brought forward and evaluated by the risk assessor. And, as in the case of chemical threats, risk assessors should be encouraged to use all available data and knowledge, to explore the range of possible risks that can be inferred from that data and knowledge, and to describe the relative scientific merits that each of the risk conclusions commands. Risk assessments so conceived and conducted can provide the same type of guidance to research and contribution to public health improvement for environmental health threats of nonchemical origin as they can for chemical threats. The development of specific methodologies will take considerable effort, but several examples have been published (19,20). And, as discussed below, risk assessment methods for many types of environmental agents, as they shall be defined below, are already



well worked out and have been applied for many years.

Let us now move to a discussion of the broad array of environmental health threats that might be profitably explored under this risk assessment framework.

### Human Health and the Environment

There is no single term (e.g., chemicals, substances, materials, objects) adequate to describe all components of the environment. I adopt the term "environmental agents" for simplicity, recognizing that this usage is not ordinary for many of the components of the environment I describe. Humans come into contact with their environments in diverse ways. Many of these contacts can harm human health, that is, they can lead to physical injuries, diseases, and deaths. Harm can take many forms, can be permanent or impermanent, and can manifest itself either at or shortly after time of contact or after a period of delay. As the term "environment" is defined it follows that the risks of most forms of human morbidity and mortality are associated with components of the environment.

Although it is true that the specific causes of most forms of human morbidity and mortality are poorly understood, it is clear that many human exposures to agents in our natural and manufactured environment increase the risks of disease and death. Indeed, I think a case can be made that the risks of most forms of human morbidity and mortality are substantially increased by exposures to environmental agents, but making this case is outside the scope of and unnecessary to the present discussion.

The phrase "increase the risks of" is adopted to avoid the problematic issue of causation. Thus, the risk assessment discussion is directed to those environmental

agents that are the proximate contributors to increased risks. In describing risks associated, for example, with pathogenic microorganisms (the proximate contributors), the risk assessment process is not required to grapple with the issue of whether the causes of those risks are the organisms themselves, the conditions that led to human exposure to them, some genetic or host factors associated with the individuals incurring the risks, or a combination of all of these. To understand these ultimate causes or sources is critically important to our attempts to manage risks. It is not critical to assessing the risks associated with human exposures to those environmental agents that are the proximate contributors to harm.

What are these environmental agents? Five broad categories, each having many members, can be identified: 1) natural and synthetic chemicals, 2) radiation, 3) physical objects, 4) pathogenic organisms, and 5) substances used as nutrients. The view of what comprises the environment that is reflected in this list is somewhat at odds with the prevailing concepts of environmental health, which focus primarily on industrial products and byproducts. There is much to be gained by adopting this much broader view of environmental health, and I hope its advantages emerge in the discussion to follow.

These broad categories of agents each contain members that, under some conditions, can increase the risk of human injury, disease, or death. As already mentioned, understanding what those conditions are and the nature, magnitude, and severity of the associated risks is for many of these agents not readily achievable using currently available scientific methods. But these are exactly the circumstances in which risk assessment comes most effectively into play, especially if it is conceived as an analytic method for ordering avail-

able information, knowledge, and uncertainties within a specific framework, using the best available scientific tools, and not as a set of rules set forth to meet specific regulatory objectives. The framework is, of course, the four-step analytic process outlined earlier; how it might be applied in the broader context that includes all five categories of environmental agents will be reviewed in the following. A thorough discussion of possible applications is not offered; I seek only to set the stage for future embellishment.

Specific examples of subgroups of agents in these five categories are listed in Table 1. Note that many of the subgroups listed contain numerous members. There are, for example, almost countless types of physical objects that are hazardous under some conditions. Natural chemicals with which people come into daily contact number in the hundreds of thousands, if not more: most of these are present as non-nutritive constituents of the human diet and most have yet to be chemically characterized, let alone studied for their hazardous properties (21).

It is probably safe to say that all of these individual environmental agents (i.e., the specific category members) can, under some conditions, increase the risk of human injury, disease, or death. It is not assumed that there is a one-to-one correspondence between exposure to environmental agents and specific risks of human injury, disease, or death. While this may be true for many cases (e.g., the risk of death from the physical trauma that occurs when a pedestrian is hit by an automobile), it is often the case that 1) exposures to many different agents are necessary to increase the risk of a specific form of harm, and 2) the risk of a specific form of harm (e.g., liver cancer or kidney disease) may be influenced by different environmental agents or combinations thereof. It is also

**Table 1.** Five categories of environmental agents that can be proximate contributors to increased human health risks<sup>a</sup>

| Pathogenic agents   | Natural and synthetic chemicals  | Radiation   | Nutritional substances   | Physical objects  |
|---|--|---|--|---|
| Many microorganisms (bacteria, fungi, viruses, parasites) | Natural products (chemicals in foods, beverages, plants, animals, insects)<br>Industrial products and by-products<br>Consumer products<br>Pesticides, agricultural chemicals<br>Medicines, medical and diagnostic devices<br>Chemicals used for clothing, shelter, other physical structures and objects<br>Tobacco and its combustion products<br>Substances used for fuels and their combustion products<br>Substances of abuse<br>By-products and wastes from above | All forms of ionizing and nonionizing radiation (including heat, sound) | Constituents of foods and beverages that are necessary for nutrition | Weapons<br>Machinery/equipment/tools<br>Moving vehicles<br>Components of physical structures<br>Water<br>Natural formation and products |

<sup>a</sup>Some subgroups contain many individual agents; naturally occurring chemicals in the diet probably make up the single largest subgroup of individual chemicals. Distinctions are made between pathogenic microorganisms that cause harm by invading the body and growing there and those that produce chemical toxins outside the body that cause harm when ingested; the latter are in the group of natural chemical products. Similarly, though the constituents of physical objects are all chemicals, the agents of harm are the objects themselves, and the harm they may create (usually some form of physical trauma) is not related to the hazards of their chemical components.

true that the nature and risk of harm occurring in exposed individuals will sometimes be influenced by certain factors, typically genetic ones, specific to those individuals, and that what constitutes a "risky exposure" for one individual will not be so for another (5).

Knowledge regarding the relationships between exposures to environmental agents and the risks they may increase is acquired in several ways. Common human experience and direct observation are the typical sources of information for many agents, especially when exposures to those agents are readily apparent to the senses and when they lead to easily recognizable injuries. Physical traumas resulting from accidents, natural disasters, warfare, or crime, and acute poisonings from certain highly toxic chemicals are examples of situations involving this means of acquiring knowledge. Actuaries are among the principal compilers of relevant data. In other cases careful scientific study is needed, often involving a combination of epidemiological and experimental work. Linking exposures to specific forms of morbidity and mortality through scientific study can sometimes be straightforward, but is often exceedingly difficult, especially when the manifestations of harm are delayed, require long-term exposures, or are significantly affected by host factors. Among the latter exposures are those to chemical agents that may increase cancer risk or that of other chronic diseases, or exposure to nutrients that can increase the risk of coronary disease (1,11).

In theory, the hazardous properties of the environmental agents will become manifest only if human exposures to them exceed some level, although it is possible that for some of them any exposure will increase risk. (How those exposures are measured and expressed will vary according to the agent.) Note that for the nutrients, failure to achieve a minimum level of exposure may also be harmful. In any case, understanding the relationships between exposures and the manifestation of harm (measured as incidence, number of cases, severity of effect or in other terms) is the risk assessor's goal. There is in theory no reason why this goal cannot be achieved for any environmental agent, although we are obviously very far from doing so. If the risk assessor can also acquire knowledge of how exposures are distributed in the human population (again using the measures of exposures appropriate to the agent of interest), then this information can be integrated with the hazard and exposure-risk information to characterize the associated health risk. This last step, risk characterization, also contains a summary of the significant uncertainties.

This all sounds relatively straightforward, but, of course, actual execution will be difficult. For many environmental agents, however, it is no more fraught with uncertainty than the current approach to carcinogen risk assessment, and for many categories of agents it is far more certain.

If risk assessment is conceived as a framework for systematic organization of available knowledge, then we can begin to develop a comprehensive picture of the relative risks posed by agents in the environment. Moreover, and this is perhaps the most important consequence of the approach suggested here, we shall become better equipped to identify the specific gaps in data and knowledge that, when filled, can most effectively reduce uncertainties. If we see as a major goal of public health research the development of an accurate understanding of the magnitudes of various environmental threats to human health, then risk assessment can be an effective element of that research program, whether it concerns risks from foodborne microbes, automobile accidents, radon, pesticides, or dietary fat.

### **The Needs of the Risk Manager**

The creation of a systematic understanding of public health threats arising from the environment that can be achieved through the development of comprehensive risk assessments directs attention to those sources of risk that, if reduced, will yield the greatest public health benefits. Risk assessment can also be applied in a predictive manner and can provide information about the possible harms associated with the introduction of new technologies. Risk assessment does not, of course, reveal how these sources of risk can be effectively managed. To achieve the latter requires knowledge of the conditions that bring about the exposures that create the risks and of the means available to alter those conditions in beneficial ways. But once the risk assessment framework is in place, equally systematic means can be developed to identify those conditions that may create excessive risks and to evaluate the relative effectiveness of various forms of intervention (everything from regulations, to warnings, to education, to economic incentives, to law enforcement, to medical measures, to political pressures). These risk management objectives are beyond the present discussion, but it seems clear that they can be pursued with the same kind of rigor I suggest can be applied to the risk assessment process.

### **Strengths and Limits of Risk Assessment as a Policy Guide**

A premise of this paper is that public

health resources should be devoted to reducing risks in at least rough proportion to the toll they take on human health, and risk assessment would seem to be the tool used to assign risks their rightful order. Seen from this perspective, risk assessment should be a principal component of public health and regulatory programs everywhere. Risk management approaches will differ, perhaps greatly, depending on local laws and customs, the availability of technical skills and the resources to deploy them, and political prerogatives. But establishing the relative needs for risk reduction programs, by continuing pursuit of comprehensive assessments of risks, should be a universal objective, and we as scientists should be willing to share our data, knowledge, and experiences to assist each other in achieving it.

We also need to work to convince governments and citizens that public health objectives should be consistent with the best available scientific and medical knowledge regarding the relative threats to our health and well being of the many risks we face and should not be established primarily upon the politically attractive trends of the moment.

Although this principle may seem the correct one to those of us concerned with the problem of identifying and characterizing health risks, certain social and cultural issues that may run contrary to it need to be considered. First, it is apparent from many studies that people's perceptions of risk often do not match those of the experts (22). In fact, when it comes to describing risks, most people do not give the probability that an adverse outcome will occur (the principal concern of the technical expert) as much weight as many other features of the risk, most of which are not (and should not) be considered by the risk assessor. Thus, it is clear that most people feel greater anxiety about low-probability events with catastrophic outcomes (such as an airplane crash) than they do about riskier activities that take one or a few lives at a time (such as automobile accidents). People want to accept no risk, no matter how tiny, unless they perceive that the risky activity or exposure provides some recognizable personal benefit. Risks imposed by others are less well tolerated than those voluntarily assumed. Risks that scientists do not understand well, and over which they may publicly squabble, are more feared than those about which scientific consensus is strong. If the risk is of natural origin it is somehow less threatening than if it is one created by human beings. There are many more attributes of a risk that influence people's perceptions of it and the intensity of the concern they feel about it (10,22).

Observations by social psychologists help us understand why people and their governments seem much more anxious about, and willing to act against, some relatively small risks that may be associated with certain types of environmental agents, such as certain industrial chemicals and pollutants, whereas they take a more relaxed attitude about risks that scientists recognize as more important from a public health perspective. This is not to say that health risks from industrial products and by-products are to be ignored—indeed, some are of significant concern and require controls—but only that the risks created by many such products are often perceived as much greater than they actually are.

Another factor complicating our efforts to devote resources to various risks to the public health in proportion to their actual impact pertains to the options available for controlling different sources of risk. Many large risks, such as those due to smoking, alcohol abuse, and poor nutrition, require intensive, multifaceted, and often long-term efforts to influence the public's attitudes and to reallocate resources. Specifying and enforcing regulatory limits on benzene emissions from a petroleum refinery or mercury levels in fish is a far easier undertaking (notwithstanding the fact that the economic consequences for manufacturers or fishermen might be quite severe). So in many societies risk reduction priorities are often based on the relative ease with which risk reduction objectives may be achieved, and this sometimes has poor correspondence to the public health importance of the risks being attacked (1).

Other factors place more emphasis on small, less well-known risks than on large, well-documented ones. Not least of these are the various food, drug, consumer product, environmental, and occupational laws that our legislatures have passed. These laws presumably reflect broad social concerns, not least of which are public perceptions of the type discussed above. Most food safety laws, for example, insist that we need to be highly risk averse when we purposefully add a substance to food, while they remain relatively silent on the much larger risks associated with natural components of the diet (8). Regulatory agencies everywhere have been denied opportunities to do much about tobacco use. These are but two examples of policies that do not

reflect current scientific understanding, but which are based on other social values.

For these and several other reasons, not least of which concern the facts that experts do not always agree on the scientific issues and that we do a wholly inadequate job in public education on these matters, we shall no doubt continue to see public health and regulatory priorities based on factors other than relative risk. It would nevertheless seem essential that those of us involved in risk assessment continue to seek the development of the data necessary to improve our understanding of risks to our health and safety (while continuing to debate just what types of data and knowledge we can best use) and to press government officials and the publics they serve to work toward risk-based priorities. And, although we need also to accept that these priorities will vary among different societies, there is no reason we should not work among ourselves toward a common approach to organizing and evaluating risk information so that, as in other areas of science, a uniform international language will exist to facilitate exchange of information and ideas.

The next step might be a concerted movement to broaden the scope of risk assessment, as well as to revise our thinking about how risk assessment should be approached, so that we can begin to assemble a comprehensive profile of the relative risks to human health posed by the large number of environmental agents, both natural and manufactured, to which humans are exposed.

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